REMARKS

In the Office Action dated June 1, 2004, Claims 40, 42-47 and 57 are pending and under consideration. The Examiner has reopened the prosecution by withdrawing the finality of the previous office action and the allowability of Claims 43-48. Claims 40, 42-47 and 57 are rejected under 35 U.S.C. §101 as allegedly lacking utility. Claims 40, 42-47 and 57 have also been rejected under 35 U.S.C. § 112, first paragraph. Claims 42 and 57 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicants, through the undersigned, wish to thank Examiner Hamud for the courtesy and assistance extended on behalf of Applicants during the telephonic interview on August 26, 2004.

By way of the instant amendment, Applicants have added new Claim 58. Support for claim 58 is found throughout the specification, e.g., on page 9, lines 4-7. No new matter is introduced.

The Examiner has rejected claims 40, 42-47 and 57 under 35 U.S.C. §101, for allegedly lacking support by either a specific and substantial asserted utility or a well established utility.

Specifically, the Examiner alleges that the instant specification does not disclose any information regarding the cognate ligand that binds to the claimed receptor, or any functional characteristics of the claimed hemopoietin receptor. While acknowledging that it is apparent that the claimed receptor is important, the Examiner is of the opinion that it is not clear as to what biological processes the receptor is involved in and whether the receptor is up-regulated or down-regulated in these processes. Thus, the Examiner contends that those skilled in the art would not know how to modulate the claimed receptor. Furthermore, the Examiner alleges that the present application does not disclose which disease or diseases the claimed

receptor could be used to treat. According to the Examiner, the specification does not establish any connection between any pathological condition and the claimed receptor.

Applicants respectfully submit that Applicants are not aware of any legal authority that requires the identification of the ligand of a receptor, or the biological processes the receptor is involved in, or the pathological condition the receptor can be used to treat, in order to establish the utility of the receptor. Nevertheless, Applicants respectfully submit that the specification and the evidence of record have provided adequate characterization of the biological function of the claimed receptor, contrary to the Examiner's allegations.

More specifically, the claimed receptor ("NR6") is explicitly characterized in the specification as a member of the hemopoietin receptor family. Other important and well-characterized members of this family include receptors for IL-2, IL-3, IL-5, G-CSF, GM-CSF, EPO and many others. As other members of this family are involved in regulation of cell proliferation and differentiation, the claimed NR receptor is believed to be involved in these activities. In fact, as stated in paragraph 5 of the Hilton Declaration previously submitted, it has been shown that a decrease in NR6 results in reduced blood cell production.

The Examiner also alleges, on page 3 of the Office Action, that the specification does not disclose any phenotype of the mice that lack this receptor. However, on page 6, the Examiner acknowledges the characterization of knockout mice in the specification, i.e., lack of NR6 is lethal during embryonic development or immediately after birth. However, the Examiner argues that the characterization of knockout mice could not be extrapolated to a "real world" use of the claimed receptor.

In response, Applicants respectfully direct the Examiner's attention to the specification on page 32, lines 7-10, which states:

> The NR6 knock-out mice studies described herein provides a useful model for this utility. There are also applications in the field of reproduction. For example, people can be tested for their NR6 status. NR6 +/- carriers might be expected to give rise to offspring with developmental problems.

Thus, contrary to the Examiner's allegation, Applicants respectfully submit that the claimed receptor is indeed useful for diagnosing or predicting a birth defect, which defines a specific "real world" use. In particular, based on the data of knockout mice provided in the specification, those skilled in the art would recognize that a married couple, both having a NR6 +/- genotype, can be alerted of the risk (e.g., possibly 25%) in having a baby with a potentially lethal birth defect.

Applicants further respectfully submit that the specification has also asserted that the claimed NR6 receptor can be employed to make agonists or antagonists for modulating the expression of the claimed receptor in those disorders associated with abnormal cell proliferation and differentiation. Based on the characterization of the claimed receptor in the specification and in the Hilton declaration, such asserted utility is certainly specific and substantial to satisfy the requirement under 35 U.S.C. §101.

In view of the foregoing, it is respectfully submitted that the claimed receptor is supported by a specific and substantial asserted utility. Therefore, the rejection of Claims 40, 42-47 and 57 under 35 U.S.C. § 101 is overcome and withdrawal thereof is respectfully requested.

Claims 40, 42-47 and 57 have also been rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner alleges that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants respectfully submit that, as the claimed invention is supported by a specific and substantial asserted utility, as discussed above, one skilled in the art would know

how to use the claimed invention without undue experimentation. As such, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

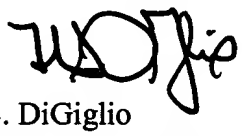
Claims 42 and 57 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Specifically, the Examiner states that a nucleic acid that hybridizes to the sequence would not encode the desired polypeptide. The Examiner suggests that the claims be amended to recite ". . . encoded by a nucleic acid which hybridizes under . . . to the complement of the nucleotide sequence of SEQ ID NO:12, 14 . . . ."

In an effort to favorably advance the prosecution of the present case, Applicants have amended Claims 42 and 57 in accordance with the suggestion by the Examiner. Accordingly, the rejection under 35 U.S.C. §112, second paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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